

**REMARKS**

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

By the present amendment, claims 1, 5, 21, and 22 are amended and claim 3 is canceled. No claims are added by the present amendment. Support for the amendments may be found throughout the specification and claims as originally filed including, but not limited to, FIGS. 1, 2, 3, 5, 6 and 7, and Para. 62. The amendments do not add new matter. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier. After amending the claims as set forth above, claims 1, 2, 4-25 and 43 will remain pending in this application.

***Alby***

Claims 21-25 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 6,241,730 issued to Alby. Applicant respectfully traverses this rejection.

Claim 21 currently recites:

A spinal stabilization element comprising:

- (a) a first segment comprising a socket extending into its proximal end, the socket defined, at least in part, by two opposing concave surfaces separated by a gap wherein *the two opposing concave surfaces are concave in a longitudinal direction of the socket*;
- (b) a second segment comprising an insert formed on a neck at a proximal end of the second segment, the insert comprising two opposing convex surfaces wherein *the two opposing convex surfaces are convex in a longitudinal direction of the insert*;
- (c) a first connector adapted to connect the stabilizing element to a first vertebra in a spinal column; and

- (d) a second connector adapted to connect the stabilizing element to a second vertebra in the spinal column;  
 wherein *the two opposing longitudinally concave surfaces retain the insert within the socket to provide a pivoting joint.*

The fact that the concave and convex surfaces are concave/convex in the longitudinal direction is supported by at least FIGS. 2-6 of the instant application. For example, in FIG. 2, reproduced below with notations, the features “longitudinally curved” and concave/convex “in a longitudinal direction” are shown:

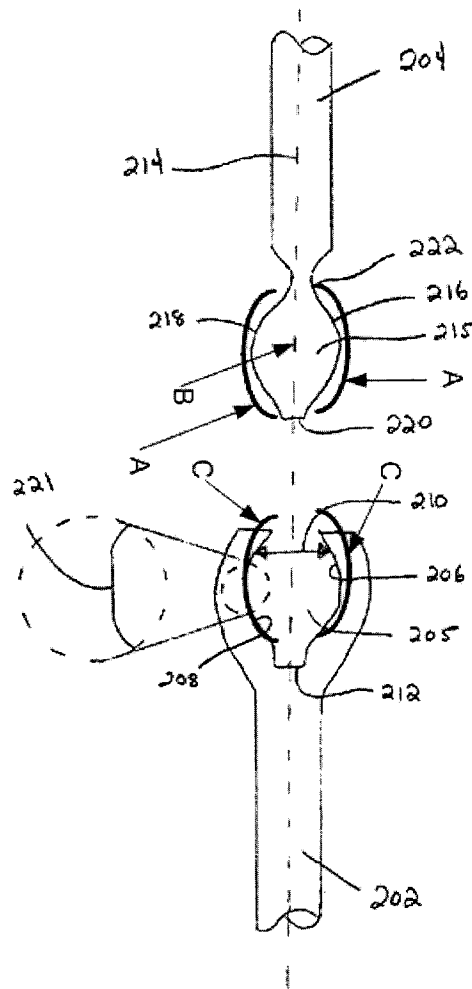


FIG. 2

Thus, as explained in paragraphs 21 and 62, FIG. 2 shows a “lateral” cross-sectional view of the stabilizing element. Element 214 is the *longitudinal* axis marked ‘B’ above. Elements 216 and 218 are convex surfaces of the insert marked ‘A’ above and elements 206 and 208 are concave surfaces of the socket marked ‘C’ above. Element 202 is labeled a first segment and element 204 is labeled a second segment. Based upon the figures and the description of the specification, the insert is convex in a longitudinal direction, and the socket is concave in the longitudinal direction, and where they engage to form the pivoting joint, it is the convex shape of the housing that holds the insert in place in the joint. Applicant asserts that Alby fails to teach such features.

Alby discloses “[a]n intervertebral link device including at least one damper element constituted by a cage and a pin.” *See* the Abstract. The intervertebral device of Alby includes a pin-in-a-cylinder construction which is described by way of FIG. 1. Thus,

the damper element 7 is made up of two elastically deformable members 7A disposed around the free end of a pin 4Ba extending one of the segments 4B constituting the rod 4. The pin 4Ba is engaged inside a housing 8a formed in a blind sleeve or cage 8 made at the free end 4Aa of the other link segment 4A. In the embodiment shown in FIG. 1, the damper element 7 comprises a rigid piston 11 formed on the pin 4Ba to constitute a joint 11 making multidirectional relative pivoting possible between the cage 8 and the pin 4Ba, at least about axes contained in a plane perpendicular to the longitudinal axis x-x' of the damper element 7 when the pin and the cage are in alignment...

The collar 11 is disposed relative to the pin 4Ba in such a manner as to receive thrust on both of its lateral faces from two sets of spring washers 12 each in the form of a pair of facing frustoconical cups of identical diameter stacked on the pin 4Ba.

Col. 3, lines 12-40, emphasis added. Note that Alby is entirely unclear as to what element is 11, and for the purposes of this response, it will be assumed to be the transverse pin on the pin 4Ba, as indicated in FIG 1.

The cylindrical shape of the inside surface of the housing (element 8a) of the cage (element 8) of Alby is also definitively shown in FIG. 1 of Alby. FIG. 1 of Alby is reproduced below:

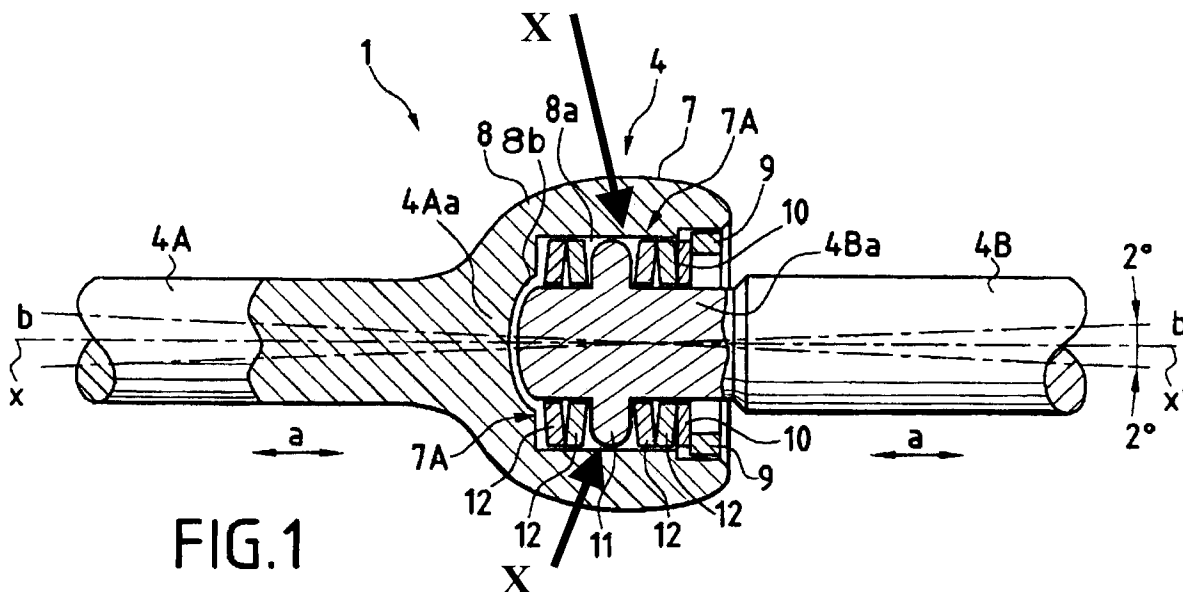


FIG. 1 shows a section view of cage 8. The inside surface of the housing 8a of the cage 8 is marked by arrows X. (Arrows added). The inside surface of the housing 8a is straight. Therefore, FIG. 1 and the related text disclose a cylindrical housing (8) with a pin (4Ba) insert.

Moreover, Alby must disclose an inside surface of the housing 8a in the shape of a cylinder. Alby discloses “[t]he collar 11 is disposed relative to the pin 4Ba in such a manner as to receive thrust on both of its lateral faces from two sets of spring washers 12 each in the form of a pair of facing frustoconical cups of identical diameter stacked on the pin 4Ba.” (Col. 3, lines 35-40). The only way the spring washers 12 of Alby can provide a “compression abutment” is if the cage 8 is a cylinder. Put another way, the spring washers 12, as depicted in FIG. 1, must have a surface to push against, which in Alby is an end of a cylinder. Thus, Alby discloses a cylinder-shaped inside surface of the housing (element 8a) of the cage (element 8) to receive a pin (4Ba). Note also that claim 1 of Alby is specifically and unambiguously directed such express elements of the pin and housing arrangement.

Furthermore, it is a washer system in Alby that retains the pin within the housing. “[T]he housing 8a of the cage 8 is *closed* by a first washer 9 secured to the cage 8 and having an inside face against which there bears a second washer 10 secured to the pin 4Ba.” Col. 3, lines 46-51, emphasis added. Thus, the only way of retaining the pin within the housing, according to Alby, is to close it in with a system of washers.

In view of the express teachings of Alby, Applicants submits that Alby fails to teach at least the elements of claim 21 of the “two opposing concave surfaces are concave in a longitudinal direction of the socket,” “the two opposing convex surfaces are convex in a longitudinal direction of the insert,” and “the two opposing longitudinally concave surfaces retain the insert within the socket to provide a pivoting joint.” Because Alby does not teach all of these elements, Applicant submits that Alby cannot be found to anticipate the presently claimed invention, and respectfully requests that the Examiner withdraw the rejections and allow the application to move forward to issuance.

### ***Alby and Middleton***

Claims 1, 2, 4-20, and 43 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Alby in view of U.S. 6,315,797 issued to Middleton. Applicant respectfully traverses this rejection.

Similar to claim 21 above, claim 1 clearly sets forth a concave socket and convex insert, presently reciting, in part:

...a first segment comprising *a socket having two opposing longitudinally concave surfaces*; and

a second segment comprising *an insert having two opposing longitudinally convex surfaces*,

wherein:

the socket and the insert engage to form a pivoting joint; and

*the two opposing longitudinally concave surface retain the insert within the socket...*

As set forth above, with respect to FIG. 2, and the attendant description in paragraph 62, it is clearly shown in the specification and drawings as originally filed, that the insert is convex in a longitudinal direction, the socket is concave in the longitudinal direction, and where they engage to form the pivoting joint, it is the convex shape of the housing that holds the insert in place in the joint.

However, as discussed above with respect to claim 21, Alby fails to teach each and every one of these elements, and furthermore, Applicant now submits that Alby fails to suggest such elements, or even give reason to the person of ordinary skill in the art to provide such elements. There simply is no teaching or suggestion of the expressly claimed elements in claim 1 of the “socket having two opposing longitudinally concave surfaces,” “an insert having two opposing longitudinally convex surfaces,” and “the two opposing longitudinally concave surface retain the insert within the socket.”

Alby does state at col. 3, line 26, that “the resulting joint 11 is of the ball-and-socket type *that also allows the cage to rotate relative to the pin about the axis x-x.*” Emphasis added. In the very next sentence, Alby defines this to mean that “the joint 11 is constituted by a collar projecting radially from *the pin 4Ba...* that is designed to come into contact with the inside surface of *the housing 8a...* In the example shown in FIG. 1, the collar 11 is an integral part of the pin 4Ba...” Emphasis added. Thus, the joint (or collar, it is unclear which) is a pin in a housing, and FIG. 1 makes it clear that the pin and housing do not include a longitudinally convex insert in a longitudinally concave socket. As such, Middleton must then be relied upon for such a teaching or suggestion; however, Middleton fails in this respect.

Middleton is not directed to a stabilizing element. Rather, Middleton is directed to an “intervertebral prosthesis include[ing] a single component, namely a disc or body member.” (Col. 3, lines 58-59). The kidney-shaped disc acts as an artificial intervertebral disc. (Col. 5, lines 1-20).

Middleton is relied upon by the Examiner for teaching a disc prosthesis or disc nucleus replacement. Meanwhile, Alby is relied upon for teaching the stabilizing element. However, as shown above, Alby fails to teach or suggest each and every element of the stabilizing element as claimed, and Middleton cannot fill in the gaps of Alby.

As such, Alby and Middleton, in combination, do not disclose at least the elements of the “socket having two opposing longitudinally concave surfaces,” “an insert having two opposing longitudinally convex surfaces,” and “the two opposing longitudinally concave surface retain the insert within the socket,” as found in claim 1. Because each and every element of the presently claimed invention is not taught or suggested by the combination of Alby and Middleton, Applicant submits that the obviousness of the presently claimed invention has not been established. Thus, Applicant respectfully requests the Examiner to withdraw the noted rejection, and allow the application to move forward to issuance.

***Alby, Middleton, and Crozet***

Claims 13 and 14 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Alby in view of Middleton and further in view of U.S. Patent No. 6,217,578, issued to Crozet *et al.* Applicant respectfully traverses this rejection.

Claims 13 and 14 depend from claim 1. As discussed above, Alby and Middleton, alone or in combination, do not disclose at least the elements of the “socket having two opposing longitudinally concave surfaces,” “an insert having two opposing longitudinally convex surfaces,” and “the two opposing longitudinally concave surface retain the insert within the socket.” Applicant now further submits that Crozet fails to fill the gaps of Alby and Middleton.

Crozet discloses “[a] spinal cross connector connect[ing] a pair of longitudinally extending rods anchored to the spine.” *See* Abstract. Crozet also discloses that “rod gripping elements ... include ... hook portions ... [and] angled holes.” (Col. 5, lines 8-11). However, the joint of the spinal cross connector of Crozet has simple flat surfaces. (FIG. 3).

Crozet fails to teach or suggest the “socket having two opposing longitudinally concave surfaces,” “an insert having two opposing longitudinally convex surfaces,” and “the two opposing longitudinally concave surface retain the insert within the socket.” In fact, there is no socket or insert described anywhere in Crozet, and Crozet cannot fill the voids of Alby and Middleton with respect to the presently claimed invention. Therefore, for at least these reasons, Applicant respectfully requests withdrawal of the rejection of claims 13 and 14, and that the application be allowed to progress toward issuance.

***Alby, Middleton, and Karpman***

Claim 15 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Alby in view of Middleton, and further in view of U.S. 6,214,012, issued to Karpman *et al.* Applicant respectfully traverses this rejection.

Claims 15 depends from claim 1. As discussed above, Alby and Middleton, alone or in combination, do not disclose at least the elements of the “socket having two opposing longitudinally concave surfaces,” “an insert having two opposing longitudinally convex surfaces,” and “the two opposing longitudinally concave surface retain the insert within the socket.” Applicant now further submits that Karpman fails to fill the gaps of Alby and Middleton.

Karpman discloses “a bone screw, including a head portion, a cannulated slotted shaft portion and a tip portion, includes an injection site for removably attaching an injection device, such as a syringe.” *See* Abstract. Hence, Karpman merely discloses a bone screw. A bone screw for injecting is not equivalent to the claimed pivoting joint.

Karpman fails to teach or suggest the “socket having two opposing longitudinally concave surfaces,” “an insert having two opposing longitudinally convex surfaces,” and “the two opposing longitudinally concave surface retain the insert within the socket.” In fact, there is no socket or insert described anywhere in Karpman, and Karpman cannot fill the voids of Alby and Middleton with respect to the presently claimed invention. Therefore, for at least these reasons,



Applicant respectfully requests withdrawal of the rejection of claim 15, and that the application be allowed to progress toward issuance.

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

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